7 Process Requirements

7.2.2 Validation of Methods

7.2.2.1 Appropriate validation studies will be conducted on all new or modified technical procedures used for laboratory activities to ensure their fitness for use. Validations will be a planned activity performed by qualified personnel with adequate resources. The selection process of new methods will consider the performance characteristics necessary to meet customer's needs and specified requirements.

Unit Supervisors/Technical Leaders shall ensure new procedures are thoroughly validated prior to use in casework by ensuring proper controls are utilized, all examiners using the procedure are properly trained, and the progress of the validation is monitored.

Validations of new procedures, modifications of existing procedures, and an initial performance check of a new piece of instrumentation require authorizations by the Supervisor(s), Technical Leader, Crime Laboratory Regional Supervisor(s), and Quality Assurance Manager. Authorization will state the instrument/method is fit for intended use.

Any significant changes occurring during the development of modified procedures will be effectively communicated to all personnel involved in the developmental process.

7.2.2.1.1 Validation procedure will include:

a) Data to support interpretation of results;
b) Establishing the guidelines required to report a test/calibration result, opinion, or interpretation;
c) Identifying limitations of the test/calibration method, reported test results, opinions, and interpretations

7.2.2.2 Modifications to validated methods and their associated data interpretations require an evaluation to confirm the changes will not have an adverse effect on the method's performance.

7.2.2.3 The range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results, the detection limit, selectivity of the method) as evaluated for fitness of use, shall be relevant to the customer's needs.

7.2.2.4 Units will maintain records of the validation. Records of the validation will be maintained for at least one accreditation cycle. Records will include:

a) the procedure used;
b) requirement specifications and/or criteria needed to verify successful validation;
c) desired performance characteristics of method and/or instrument;
d) the results of the validation; and

e) a statement from the Technical Leader verifying the technical procedure is fit for its intended use.

7.2.2.5 Prior to implementation of a validated method new to the laboratory, the reliability of the method shall be demonstrated in-house against any documented performance characteristics of that method. These records must be maintained for future reference. Each laboratory must complete and maintain performance based validation studies (such as sensitivity and precision) independent of one another while basic validation studies may be shared amongst all locations within a laboratory system. Supporting independent documentation that summarizes the results of each study must be prepared and maintained at the laboratory site.

7.2.2.6 If applicable, all examiners who will be utilizing new or validated procedures will be given competency samples to analyze prior to introduction of the method into casework. If necessary, the final validation will demonstrate the ability of examiners to correctly use and interpret the results. Results may be captured in an official TBI Report.

7.2.2.7 Quantitative procedures will be checked to ensure that the instrument is calibrated, linear in the working range, and possesses a high degree of accuracy and precision at concentrations which are representative of the casework samples.

7.2.2.8 Qualitative procedures involving interpretation by the examiner must be specific, reliable, reproducible, and yield results free of possible misidentification errors.